K070022

APR 20 2007

**510(k) Summary:**
**Mistral one stage screw-type dental implant**

**Company Name:**
MIS Implant Technologies Ltd.

**Contact Person:**

Iman Khorshid
Quality Manager
Telephone: +972-4-980-9966
Fax: +972-4-980-9944
E-mail: iman@mis-implants.com

**Authorized US Agent:**

Motti Weisman – VP Marketing
MIS Implants Technologies Inc.
278 Broadway
Elmwood Park, NJ 07407

Phone: (201) 797-9144
Fax: (201) 797-9145
E-mail: mis.service@verizon.net

**Date prepared:** October 26, 2006

**Trade Name:**
Mistral One Stage Screw-type Dental Implant

**Classification:**
**Classification name:** Endosseous Dental Implant
**Common/usual name:** Endosseous Dental Implant
**Product Code:** DZE
**Regulation No.:** 872.3640
**Class: II**
**Panel identification:** Dental Devices Panel

**Predicate Device:**
**One stage implant as part of MIS Dental Implant System**, MIS Implant Technologies, Shlomi, Israel, cleared under 510(k) no. **K040807**.

**Description of the device:**
The Mistral is a one stage, screw-type, internal octagon dental implant and is provided in the following range of dimensions:

- Diameters: 3.75, 4.10 and 4.80 mm
- Length: 8, 10, 11.50, 13 and 16 mm

All implants are manufactured from medical grade 5 pure titanium, which meets requirements of standard ASTM F136.

The required surface roughness and microgeometry of the implants is achieved by blasting sand particles and acid etching. Blasted surfaces archive more bone contact with the implant surface.

**Indications for Use:**
The Mistral one stage screw-type dental implant is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function.

**Substantial Equivalence:**
The Mistral single stage screw-type dental implant has the same intended use as the original one stage implant, cleared as part of the MIS dental Implant System under 510(k) no. K040807 and has equivalent performance characteristics. It is therefore substantially equivalent to that device.

**Conclusion:**
The evaluation of the Mistral single stage screw-type dental implant does not raise any additional concerns regarding safety and effectivity and may therefore be considered substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 20 2007

MIS Implant Technologies, Limited
C/O Mr. Motti Weisman
Vice President Marketing
278 Broadway
Elmwood Park, New Jersey 07407

Re: K070022
Trade/Device Name: Mistral One Stage Screw-Type Dental Implant
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: April 9, 2007
Received: April 19, 2007

Dear Mr. Weisman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known):

Device Name: Mistral one stage screw-type dental implant

Indications For Use:

The Mistral one stage screw-type dental implant is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K070220